



WEBINAR SERIES:

Regulatory Approaches for Agricultural Applications of Animal Biotechnology

Session 1 • September 8-9, 2020



Session I: Food safety aspects of regulations for genetically engineered/modified animals

Summary of presentations

Maria Dagli

University of São Paulo

Ex - CTNBio member and vice-president

Keynote

CODEX - Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Standards Australia -New Zealand (FSANZ)

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS

CAC/GL 68-2008

SECTION 1 - SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits¹.
2. The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:
 - animal welfare;
 - ethical, moral and socio-economical aspects;
 - environmental risks related to the environmental release of recombinant-DNA animals used in food production;
 - the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.
3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods, whatever their origin, have been assessed scientifically in a manner that would fully characterize all risk associated with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.



Keynote

CODEX - Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Standards Australia -New Zealand (FSANZ)

- **Background**

- CAC/GL 44-2003 and CAC/GL 68-2008 (FAO – WHO)

- **Guidelines scope**

- The guideline applies to recombinant DNA animals in general
- Plant guidelines used as a model
- Addresses only food safety and nutritional issues



Keynote CODEX - Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Safety Australia New Zealand (FSANZ)

- **Basic Codex framework**
 - Phenotypic information
 - Molecular characterisation
 - Assessment of new substances
 - Whole food assessment
 - Composition analysis
 - Assessment of nutritional impact



Keynote CODEX - Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Safety Australia New Zealand (FSANZ)

highlights

- Case by case analysis
- Comparisons of recombinant DNA animals with conventional counterparts
- Focus on intended and eventually unintended changes



Regulatory Approaches in Different Countries

- **Argentina** - Andrés Maggi, SENASA
- **Brazil** - Flavio Finardi, CTNBio
- **Australia/New Zealand** - Lisa Kelly, FSANZ
- **Philippines** - Claro Mingala, Philippine Carabao Center
- **Canada** - Gaetano Cianciarelli, Health Canada
- **United States** - Kimon Kanelakis, Food and Drug Administration
- **African Union** - Inter-African Bureau for Animal Resources (AU-IBAR) - Edward Musiwa

Regulatory Approaches in Different Countries

Country	Argentina	Brazil	Australia	Phillipines	Canada	USA
Regulatory Organ	SENASA	CTNBio	Regulatory Framework (Office of the Gene Technology Regulator) FSANZ, DAWR NICNAS, APVMA, TGA	Dept of Agriculture, Bureau of Animal Industry	Canadian Food Inspection Agency, Health Canada, ECCC, HC, DFO, AAFC, GAC, ISED	FDA
Specific regulation for GM animals?	No	No	No	No	No	No
Codex alimentarius?	Yes	RN 24 Codex alimentarius, EFSA document 2012 and others	Yes	Yes	Yes	Yes
GM food animal commercially approved?	No	No	No	No	Yes	Yes
Regulation for genome edited animals?	Yes	Yes	No	No	CEPA (Canadian Environmental Protection Act)	Yes

African Union - Inter-African Bureau for Animal Resources (AU-IBAR) - Edward Musiwa

- AU does not set standards and regulations on biosafety and animal biotechnology but supports member states to develop policies and capacity for GMO.
- Promotes harmonization on safety assessment approaches
- Facilitates international discussions on genetically modified animals for food.





Photo Competition to Commemorate World Development Information Day

“Prospects for Growth through Livestock”

The competition deadline is 30th September, 2020



African Union



Africa Blue Economy Strategy

“
Providing
leadership in the
development of
animal resources
in Africa
”

Current Programmes and Projects



2017 - 2021
Live2Africa

2018 - 2019
RAFIP

AU-IBAR Current Publications



2018
Strategic Plan 2018-2023



2015
**The Livestock Development
Strategy for Africa (LiDeSA)**

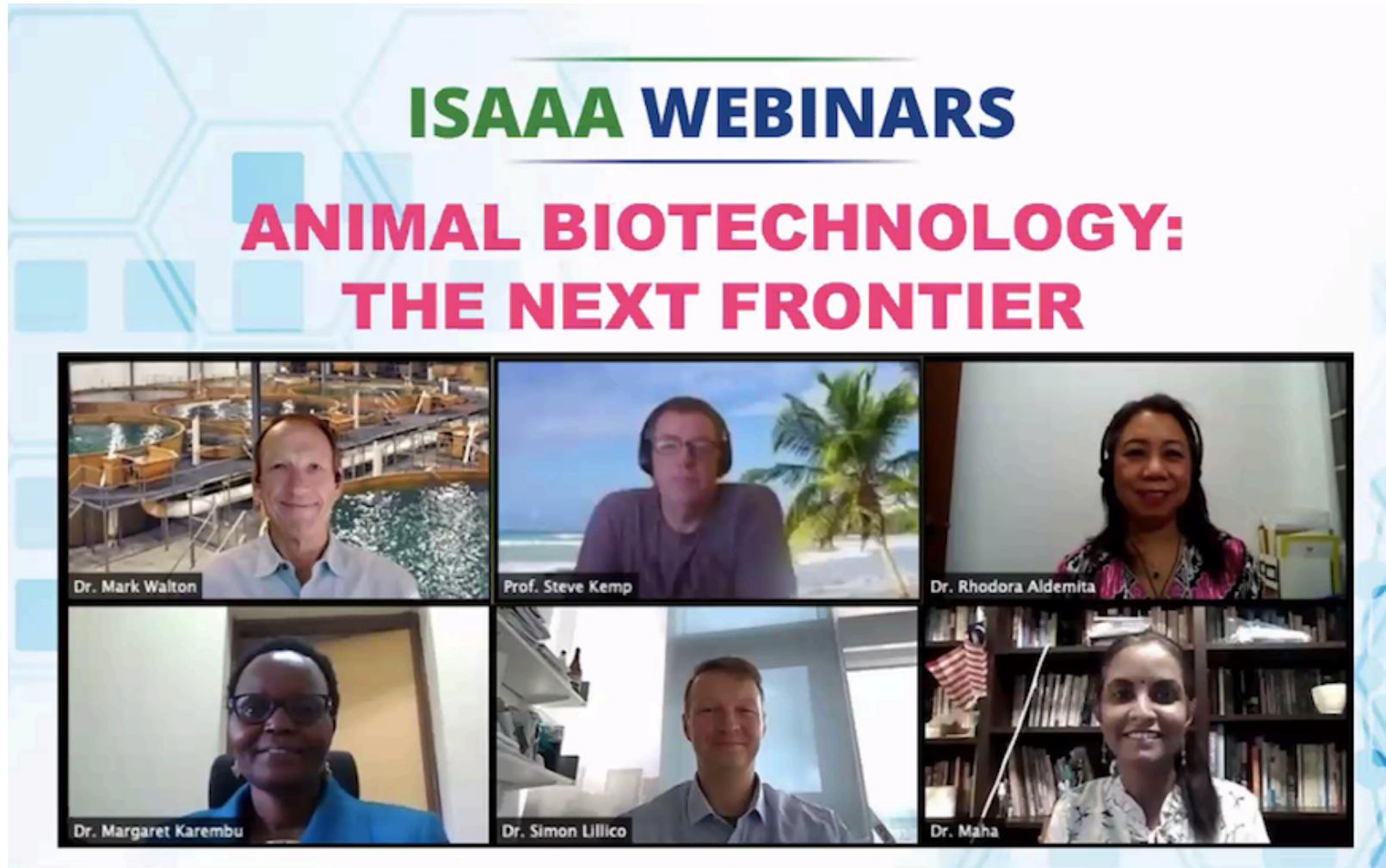
Press Release - 4th Africa Animal Welfare Conference

On 09 September 2020.

From 7-10 September, 2020, Animal Welfare stakeholders and representatives from several organization will participate



ISAAA WEBINARS – Margareth Karembu Animal Biotechnology – the next frontier



ISAAA WEBINARS – Margareth Karembu

Animal Biotechnology – the next frontier

- 541 attendees, from 61 countries.
- Poll report – 3 top messages:
 - Perceived acceptance of GM animals is high
 - International progress on biosafety policy and gene drive are topics of high interest to stakeholders in the animal biotech community
 - Scientists and relevant government departments are the preferred biosafety communicators.



PRESENTATIONS 09 09

- **USDA – FSIS** (FOOD SAFETY AND INSPECTION SERVICE) – Melanie Abley
 - HACCP – Hazard Analysis and Critical Control Points (80000 samples for microbial testing a year!)
 - Science based, risk based decisions.
- **Industry Perspective** - Christine Alvarado, Arm and Hammer Animal and Food Production
 - Safety of food , control of pathogens, understanding how and where the contaminations occur to control them – biomapping.
 - Test test test! Use data analytics to control the process.
- European Union – **EFSA** - Antonio Fernandez Dumont, EFSA
 - EFSA document (Scientific Opinion) – 2012
 - HAZARD and Risk characterization
 - Comparisons with conventional counterparts

Keynote CODEX - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Standards Australia -New Zealand (FSANZ)

- **Background**
- CAC-GL – Taskforce on Foods derived from Biotechnology adopted in 2008
- The guideline applies to recombinant DNA animals in general
- Plant guideline used as a model
- Informed by two FAO/WHO expert consultations:
 - Safety assessment of food derived from GM animals, including fish (2003)
 - Safety assessment of food derived from recombinant DNA animals (2007)



Keynote CODEX - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Safety Australia New Zealand (FSANZ)

- **Guideline scope**
- Addresses only food safety and nutritional issues
- Approach could be applied to foods from other animals altered by other techniques. (potentially it could be applied to food derived from genetically edited animals).



Keynote CODEX - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Safety Australia New Zealand (FSANZ)

- **Basic Codex framework**
- Phenotypic information
- Molecular characterisation
- Assessment of new substances
- Whole food assessment
 - Composition analysis
 - Assessment of nutritional impact



Keynote CODEX - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant- DNA Animals

Lisa Kelly, Food Safety Australia New Zealand (FSANZ)

IMPORTANT

CASE BY CASE ANALYSIS,

COMPARISONS TO CONVENTIONAL FOODS,

FOCUS ON INTENDED AND EVENTUALLY UNINTENDED CHANGES



Regulatory Approaches in Different Countries

- Argentina - Andrés Maggi, SENASA
- Brazil - Flavio Finardi, CTNBio
- Australia/New Zealand - Lisa Kelly, FSANZ
- Philippines - Claro Mingala, Philippine Carabao Center
- Canada - Gaetano Cianciarelli, Health Canada
- United States - Kimon Kanelakis, Food and Drug Administration
- Africa Union policies, strategies and guidance documents that identify science, technology and innovation as important vehicle for socio-economic development – John Oppomg-Otoo, AU-IBAR - Inter-African Bureau for Animal Resources (AU-IBAR)

Argentina – Andres Maggi

- Responsible organ = SENASA (Servicio Nacional de Sanidad)
- Resolution SENASA 412/02 (Fundaments and criteria for the assessment of food/feed derived from GMO).
- Resolution SENASA 1265/99 (Advisory technical committee on the use of genetically modified organisms).
- There is no specific laws for animals
- Follow the CODEX guidelines, case by case basis.
- Risk assessment must prove that it is as safe and nutritive as conventional species.
- So far no GM animals have been evaluated in Argentina



Brazil – Flavio Finardi

- Responsible organ: CTNBio, from the Ministry of Science, Technology and Innovation of Brazil
- Law 11105, from March 25, 2005 + Normative Resolutions
- RN 16 for New breeding technologies (ex. gene editing)
- Plants, microorganisms, vaccines, animals.
- So far, 182 commercial approvals
- 1 animal considered non-GMOs
- No specific normative for GM animals.
- Follows Codex Alimentarius for plants



Australia/New Zealand - Lisa Kelly, FSANZ

- Regulatory Framework - Gene Technology Regulator
- DAWR, NICNAS, APVMA, TGA, FSANZ
- Gene Technology Scheme (Gene Technology Act 2000) (Australia)
- Joint food Regulation System (Australia New Zealand Food Standards Code – 1991) (Australia and New Zealand)
- Based on Codex alimentarius
- Data requirements are generic (not specific for animals)
- So far, no GM animals received (74 GM animals with potential commercial application)



Philippines - Claro Mingala, Philippine Carabao Center

- Republic act 10611 – Food safety Act 2013
- FAO , 1999
- Department of Agriculture, Bureau of Animal Industry
- Concerns about toxins and allergies provoked by GM foods
- Nutritional and toxicological analysis of GM organisms
- No GM food animals in the Market.
- Regulatory GM animals policy on the way.



Canada - Gaetano Cianciarelli, Health Canada

- Organs: Canadian Food Inspection Agency, Health Canada, ECCC, HC, DFO, AAFC, GAC, ISED
- **Product** based system
- Pre Market safety assessment
- Risk based approach – Codex alimentarius.
- Authorization process – novel food assessment, livestock assessment, environmental assessment – if all approved – COMMERCIALIZATION.
- Regulating gene-edited animals – CEPA (Canadian Environmental Protection Act).



United States - Kimon Kanelakis

Food and Drug Administration

- IGA – Intentional Genomic Alterations - recombinant DNA or gene edited
- Food safety evaluations according to Codex Alimentarius.
- CAC/GL 44-2003 and CAC/GL 68 2008
- Hazard Identification and characterization
- Phenotypic characterization



Inter-African Bureau for Animal Resources (AU-IBAR) - John Oppomg-Otoo, AU-IBAR - Edward Musiwa

- Started in 1951 - IBED – Interafrican Bureau of Epizootic Diseases
- 1970 - Interafrican Bureau for Animal Resources
- African Union – IBAR and AUC – DREA from 2003.
- Recommendation – Biotechnology and its importance in various sectors.
- AU does not set standards and regulations on biosafety and animal biotechnology but supports member states to develop policies and capacity for GMO.
- Promotes harmonization on safety assessment approaches
- Facilitate international discussions on genetically modified animals for food.



Thank you!